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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,807	01/11/2002	Xuanchuan Yu	LEX-0298-USA	8020

7590

08/12/2002

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EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/044,807

Applicant(s)

YU ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the title. Titles should be descriptive and not use the words “novel” or “new”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a well established utility for either the nucleic acid molecule of SEQ ID NO: 1 or any nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2. Furthermore, the claimed invention is not supported by an asserted utility based on either a demonstrated function for the protein of SEQ ID NO: 2 or by a deduced function for said protein supported by homology to known proteins.

The inferred utility for the protein of SEQ ID NO: 2, based on “shared structural similarity”, is as a metalloprotease (p17 line 27-p18 line 2 and Title). The first 30% of SEQ ID NO: 2 has 99% identity with ADAM-TSR1, a metalloprotease with thrombospondin type I modules (Hirohata et al, 2001). However, this N-terminal 30% of SEQ ID NO: 2 does not include a catalytic domain. Furthermore, SEQ ID NO: 2 does not contain the conserved His-Glu-Xxx-Xxx-His-Xxx-Xxx-His motif for the catalytic domain of metalloproteases (Fahrenholz et al, 2000). SEQ ID NO: 2 also lacks the Pro-Arg-Cys-Gly-Xxx-Pro motif for the propeptide domain of metalloproteases (Massova et al, 1998). Sequence searches showed no consistent homology for the full-length SEQ ID NO: 2 with metalloproteases. One polynucleotide

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sequence showing high homology to SEQ ID NO: 1, 98% over the full-length of SEQ ID NO: 1, encodes a thrombospondin-like protein (WO200121658-A1 SEQ ID NO: 18; Gene #8; p26-30 and Figs 4-5). A second polynucleotide sequence showing high homology to SEQ ID NO: 1, 98% over the full-length of SEQ ID NO: 1, encodes a hypothetical protein from *C. elegans* of unknown function that is not a metalloprotease (WO200154474-A2 SEQ ID NO: 134; Gene #124; Table 1 p76 and Table 2 p226). A third protein, TANGO 224, has a thrombospondin domain but is not a metalloprotease (WO200039284-A1 SEQ ID NO: 224; Abstract and pages 52-56). Thus, the identity of the polynucleotide sequence of SEQ ID NO: 1, or any other polynucleotide sequence encoding the protein of SEQ ID NO: 2, as encoding a metalloprotease is not supported.

As stated in the specification, the proposed utilities for the protein encoded by SEQ ID NO: 1, SEQ ID NO: 2, are: microarrays, or other assay, to screen genetic material from patients; identification of mutations associated with SEQ ID NO: 2; diagnostic assays; preparation of anti-sense oligonucleotides derived from SEQ ID NO: 2; hybridization assays; library screening; characterization of genomic clones; PCR; restriction fragment length polymorphism analysis; isolation of full-length cDNA; preparation of fusion proteins; preparation of antibodies; as therapeutics (page 8-16); analysis of protein evolution; and preparation of transgenic animals (page 18-21). Each of these utilities is an application which would apply to every member of a general class of materials and/or is a use only for further research to determine a use for SEQ ID NO: 1 or the protein encoded thereby. As such, these asserted utilities are not specific (for those applicable to all human DNAs) or not substantial because the use of SEQ ID NO: 2 therein is

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only potential and not in currently available in practical form. Therefore, Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by an established utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a demonstrated, deduced, or well established function for the protein of SEQ ID NO: 2, or encoded by SEQ ID NO: 1, for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696.

The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


REBECCA E. PRODY
PRIMARY EXAMINER
GROUP 1800